

and that the graft can be a bundle of strands (col. 6, lines 60-61), (with regard to claim 9, the Examiner points to col. 4 lines 20-26). The Examiner states that McGuire additionally teaches that fixation devices are used in "kits" for ligament repair (col. 5, lines 17-22). The Examiner states that regarding claim 35, McGuire discloses drilling holes in the bone plugs, but does not explicitly disclose having pre-attached sutures to the ligament. The Examiner contends that it would have been obvious to one of ordinary skill in the art to have pre-attached sutures to the ligament in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery. A brief analysis of McGuire is set forth below.

McGuire is directed to cruciate ligament reconstruction with tibial drill guide. McGuire teaches at least one ligament replacement extended between two bone plugs and fixed within each of two bone tunnels in the bones of a joint using interference screws. McGuire teaches that the bone blocks for use in the composite graft can be autogenous bone, allograft fresh frozen or freeze-dried bone, or a synthetic material. Regarding the ligament replacement material, McGuire discloses the preferable use of autogenous tendon, or that alternative ligament materials such as allograft human tissue or artificial fibers can be used. In view of the following, this rejection is respectfully traversed.

Anticipation under 35 USC §102(b) requires that a single prior art reference teach each and every element of the claimed invention. Claims 1-4, and 7-11, require a graft including a graft material having a first and second set of sutures where the graft including sutures is preserved, non-autologous, and provided in sterile packaging. McGuire does not teach a graft material having a first and second set of sutures where the graft together with sutures is preserved and provided in sterile packaging. Thus, McGuire does not teach each and every element of the claimed invention. Accordingly, the Examiner is requested to withdraw this rejection with regard to claims 1-4, and 7-11.

Claims 12, 14, and 37, require a graft including a bundle of graft material strands where the bundle has a proximal and a distal end with a first set of sutures securing a first bone plug to the proximal end and a second set of sutures securing a second bone plug to the distal end, where the graft including bone plugs and sutures is preserved and provided in sterile packaging. McGuire does not teach a graft material having a first and second set of sutures securing a first and second bone

plug where the graft together with sutures and bone plugs, is preserved and provided in sterile packaging. Thus, McGuire does not teach each and every element of the claimed invention. Accordingly, the Examiner is requested to withdraw this rejection with regard to claims 12 and 14.

Claims 35-36 and 38, require a kit including a sterile, packaged, prepared, non-autologous, replacement ligament having pre-attached sutures and having a graft fixation device. McGuire does not teach a kit including a sterile, packaged, prepared, non-autologous, replacement ligament having pre-attached sutures, let alone a kit including a sterile, packaged, prepared, non-autologous, replacement ligament having pre-attached sutures and a graft fixation device. Thus, McGuire does not teach each and every element of the claimed invention. Accordingly, the Examiner is requested to withdraw this rejection with regard to claims 35-36, and 38.

Regarding the rejection of the claims under 35 USC §103, Applicant's submit that McGuire does not suggest the presently claimed graft. In view of the following, this rejection is respectfully traversed.

It is submitted that the Examiner has not established a proper case of *prima facia* obviousness. A proper case of *prima facia* obviousness under 35 U.S.C. §103, requires that the prior art as a whole, must suggest the desirability of making the claimed combination and provide a reasonable expectation of success. The Examiner contends that it would have been obvious to one of ordinary skill in the art to have pre-attached sutures to the ligament in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery. The Examiner states that McGuire additionally teaches that fixation devices are used in "kits" for ligament repair (col. 5, lines 17-22).

Present claims 1-4, and 7-11 require a replacement package including non-autologous graft material having a first set of sutures attached to the proximal end and a second set of sutures attached to the distal end, where the graft with sutures is preserved and provided in sterile packaging.

Present claims 12-15, and 37, require a replacement ligament including non-autologous graft material strands having a proximal end and a distal end, and a first set of sutures securing a first bone plug to the proximal end, and a second set of sutures securing a second bone plug to the distal end.

Present claims 35-36, and 38, require a kit for replacing a damaged ligament including a sterile packaged prepared non-autologous replacement ligament having pre-attached sutures for aiding insertion into the patient, and a graft fixation device.

McGuire does not suggest the desirability of making the claimed replacement package, as required to establish a proper case of *prima facie* obviousness under 35 USC §103. Regarding claims 1-4 and 7-11, McGuire does not suggest a sterile packaged prepared replacement ligament having pre-attached sutures. Rather, McGuire teaches, in the "Detailed Description of The Preferred Embodiments" that the composite graft is formed, i.e. sutures attached and/or attachment of bone plugs, during the course of the cruciate ligament reconstruction surgical operation. At col. 5, lines 6-7, McGuire states that sutures are also used through the suture holes to attach the tendon to each of the bone plugs. McGuire does not suggest securing sutures to the graft material in the absence of bone plugs, or securing sutures to the graft material and providing a sterile prepackaged replacement graft. The Examiner states that at col. 5, lines 17-22 (it appears that the Examiner may be referring to lines 14-16), McGuire teaches that fixation devices are used in "kits" for ligament repair. This is incorrect. McGuire teaches, at lines 14-16, only that "further embodiments of the invention may substitute or combine man made or artificial fibers or human tissue for the tendons for use as the ligament replacement." McGuire does not teach or suggest a sterile, packaged, replacement ligament as required by the present claims.

Regarding claims 12-15 and 37, McGuire does not suggest a sterile, packaged, prepared replacement ligament having pre-attached sutures, let alone a sterile, packaged, prepared replacement ligament having a first set of sutures securing a first bone plug to the proximal end, and a second set of sutures securing a second bone plug to the distal end, as required by these claims.

Regarding claims 35-36, and 38, again McGuire does not suggest a replacement kit including a sterile, packaged, prepared non-autologous replacement ligament having pre-attached sutures, and a graft fixation device.

In view of the above, it is submitted that a proper case of *prima facie* obviousness has not been established, and that nothing in McGuire, suggest claims 1-4, 7-12, and 35-38, within the meaning of 35 U.S.C. § 103. Accordingly, the examiner is respectfully requested to withdraw this rejection.

**II. *At page 2 of the Final Office Action, the Examiner has rejected claim 15 under 35 U.S.C. §103 as obvious over McGuire '669 in view of Prewett et al. '810.***

The Examiner states that in view of McGuire it would have been obvious to one of ordinary skill in the art to have pre-attached sutures to the ligament in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery. With regard to claim 15, the Examiner states that McGuire does not disclose lyophilization of allografts, and that Prewett et al. teaches that graft tissue strength can be maintained by freezing or lyophilizing when packaging. The Examiner points to col. 6 lines 31-45 of Prewett. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to lyophilize an allograft as taught by Prewett et al. for the graft of McGuire in order to provide a durable replacement.

A brief analysis of McGuire is set forth above. Prewett et al. is directed to a method of processing fibrous connective tissue to reduce its immunogenicity upon surgical implantation into a mammal. Prewett et al. teaches that lyophilization or freezing will prevent the degradation of mechanical strength, which degradation occurs after removal of antigen and/or debris.

It is submitted that Prewett does not cure the deficiencies of McGuire since Prewett also does not suggest a sterile, packaged, prepared, non-autologous, replacement ligament having pre-attached sutures, let alone a sterile, packaged, prepared replacement ligament having a first set of sutures securing a first bone plug to the proximal end, and a second set of sutures securing a second bone plug to the distal end, as required by present claim 15.

In view of the arguments set forth in reference to McGuire and as set forth above, it is submitted that a proper case of *prima facie* obviousness has not been established, and that nothing in McGuire or Prewett, taken alone or together, suggest claim 15, within the meaning of 35 U.S.C. § 103. Accordingly, the examiner is respectfully requested to withdraw this rejection.

***III. At page 2 of the Final Office Action, the Examiner has rejected claims 5, 6, 13, and 39, under 35 U.S.C. §103 as obvious over McGuire '669 in view of Schmieding '561.***

The Examiner states that in view of McGuire it would have been obvious to one of ordinary skill in the art to have pre-attached sutures to the ligament in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery. With regard to claim 15, the Examiner states that McGuire does not disclose the use of long strand sutures and various lengths of ligaments, and that Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient (col. 5, lines 25-32) and that Schmieding also teaches the use of various lengths for ligament repairs (col. 4, lines 56-66). The Examiner concludes that it would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

A brief analysis of McGuire is set forth above. Schmieding is directed to a work station for preparing a bone-tendon-bone core graft. Schmieding discloses preparing a triple strand autograft only.

Present claims 5 and 6 are dependent on present independent claim 1 and require a sterile, preserved, packaged, non-autologous, graft material having pre-attached sutures. Claim 13 further requires that the first set of sutures secures a first bone plug to the proximal end of the graft material and that the second set of sutures secures a second bone plug to the distal end of the graft material. Claim 39 requires a kit including a plurality of sterile, packaged, non-autologous, prepared replacement ligaments each having a different length and each having pre-attached sutures; and a graft fixation device.

It is submitted that Schmieding does not cure the deficiencies of McGuire since Schmieding also does not suggest a sterile, packaged, prepared, non-autologous, replacement ligament having pre-attached sutures, as required by the present claims. Further, regarding claim 39, Schmieding also does not suggest a kit where a plurality of preserved ligaments of various lengths are provided. Schmieding disclosed only autograft, and does not suggest a non-autologous graft.

In view of the arguments set forth in reference to McGuire and as set forth above, it is submitted that a proper case of *prima facie* obviousness has not been established, and that nothing in McGuire or Schmieding, taken alone or together, suggest claims 5, 6, 13, and /or 39, within the meaning of 35 U.S.C. § 103. Accordingly, the examiner is respectfully requested to withdraw this rejection.

It is submitted that claims 1-15, and 35-39, are in condition for immediate allowance and early notice to that effect is respectfully requested. The Examiner is invited to contact the undersigned at her telephone number on any questions that may arise.

Respectfully submitted,  
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